

# PATENT COOPERATION TREATY

PCT

## NOTIFICATION OF ELECTION (PCT Rule 61.2)

From the INTERNATIONAL BUREAU

To:

United States Patent and Trademark  
Office  
(Box PCT)  
Crystal Plaza 2  
Washington, DC 20231  
ÉTATS-UNIS D'AMÉRIQUE

in its capacity as elected Office

Date of mailing (day/month/year) <b>19 October 1998 (19.10.98)</b>	
International application No. <b>PCT/US98/03178</b>	Applicant's or agent's file reference <b>5063.01</b>
International filing date (day/month/year) <b>19 February 1998 (19.02.98)</b>	Priority date (day/month/year) <b>19 February 1997 (19.02.97)</b>
Applicant <b>CONDADO, Jose Antonio R.</b>	

1. The designated Office is hereby notified of its election made:

in the demand filed with the International Preliminary Examining Authority on:

**18 September 1998 (18.09.98)**

in a notice effecting later election filed with the International Bureau on:

\_\_\_\_\_

2. The election  was

was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland  Facsimile No.: (41-22) 740.14.35	Authorized officer  Lazar Joseph Panakal  Telephone No.: (41-22) 338.83.38
---	--

## PATENT COOPERATION TREATY

PCT

REC'D 21 JUN 1999

WIPO PCT

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT PCT

## (PCT Article 36 and Rule 70)

Applicant's or agent's file reference 5063.01	<b>FOR FURTHER ACTION</b> See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/US98/03178	International filing date (day/month/year) 19 FEBRUARY 1998	Priority date (day/month/year) 19 FEBRUARY 1997
International Patent Classification (IPC) or national classification and IPC IPC(6): A61M 25/00; and US Cl.: 604/280		
Applicant CONDADO MEDICAL DEVICES CORPORATION		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

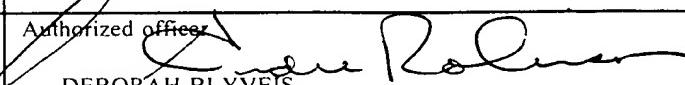
2. This REPORT consists of a total of 5 sheets.

This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority. (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 0 sheets.

3. This report contains indications relating to the following items:

- I  Basis of the report
- II  Priority
- III  Non-establishment of report with regard to novelty, inventive step or industrial applicability
- IV  Lack of unity of invention
- V  Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI  Certain documents cited
- VII  Certain defects in the international application
- VIII  Certain observations on the international application

Date of submission of the demand 18 SEPTEMBER 1998	Date of completion of this report 04 JUNE 1999
Name and mailing address of the IPEA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231	Authorized officer  DEBORAH BLYVEIS
Facsimile No. (703) 305-3230	Telephone No. (703) 308-2110

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US98/03178

**I. Basis of the report**

1. This report has been drawn on the basis of (*Substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain*

 the international application as originally filed. the description, pages 1-78, as originally filed.pages NONE, filed with the demand.pages NONE, filed with the letter of \_\_\_\_\_.pages       , filed with the letter of \_\_\_\_\_. the claims, Nos. 1-119, as originally filed.Nos. NONE, as amended under Article 19.Nos. NONE, filed with the demand.Nos. NONE, filed with the letter of \_\_\_\_\_.Nos.       , filed with the letter of \_\_\_\_\_. the drawings, sheets/fig 1-60, as originally filed.sheets/fig NONE, filed with the demand.sheets/fig NONE, filed with the letter of \_\_\_\_\_.sheets/fig       , filed with the letter of \_\_\_\_\_.

2. The amendments have resulted in the cancellation of:

 the description, pages NONE. the claims, Nos. NONE. the drawings, sheets/fig NONE.

3.  This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the ~~Supplemental Box~~ Additional observations below (Rule 70.2(c)).

4. Additional observations, if necessary:

NONE

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US98/03178

**III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

The question whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been and will not be examined in respect of:

- the entire international application.
- claims Nos. 38-49, 53-56, 61, 79-81, 86, 87, 93, 116-119

because:

- the said international application, or the said claim Nos. relate to the following subject matter which does not require international preliminary examination (*specify*).

- the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*).

- the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

- no international search report has been established for said claims Nos. (See Attached).

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US98/03178

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement****1. STATEMENT**

Novelty (N)	Claims <u>(Please See supplemental sheet)</u>	YES
	Claims <u>(Please See supplemental sheet)</u>	NO
Inventive Step (IS)	Claims <u>(Please See supplemental sheet)</u>	YES
	Claims <u>(Please See supplemental sheet)</u>	NO
Industrial Applicability (IA)	Claims <u>(Please See supplemental sheet)</u>	YES
	Claims <u>(Please See supplemental sheet)</u>	NO

**2. CITATIONS AND EXPLANATIONS**

Claims 1-3, 6, 7, 10, 11, 13-34, 76-78 and 82 lack novelty under PCT Article 33(2) as being anticipated by Weinberger. Weinberger discloses a catheter (5) with a conduit (6), and a bulk (5a).

Claims 1-4 lack novelty under PCT Article 33(2) as being anticipated by Calderon. Calderon discloses a catheter with a conduit, and a plurality of bulks (56)(22).

Claims 95, 96, 101, 102, 107-110, 112 and 113 lack novelty under PCT Article 33(2) as being anticipated by Liprie. Liprie discloses a drive cable (110) with a radioactive portion (10).

Claims 5, 8, 9, 12, 35-37, 50-52, 57-60, 62-68, 83-85, 88-92, 94, 97-100, 103-106, 111, 114 and 115 meet the criteria set out in PCT Article 33(2)-(4) because the prior art does not teach or fairly suggest the donut radioactive parts.

----- NEW CITATIONS -----

NONE

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US98/03178

**Supplemental Box**

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: Boxes I - VIII

Sheet 10

**III. NON-ESTABLISHMENT OF REPORT:**

No international search report has been established for claim numbers 38-49, 53-56, 61, 69-75, 79-81, 86, 87, 93, 116-119.

**V. 1. REASONED STATEMENTS:**

The report as to Novelty was positive (YES) with respect to claims 5, 8, 9, 12, 35-37, 50-52, 57-60, 62-68, 83-85, 88-92, 94, 97-100, 103-106, 111, 114, 115.

The report as to Novelty was negative (NO) with respect to claims 1-4, 6, 7, 10, 11, 13-34, 76-78, 82, 95, 96, 101, 102, 107-110, 112, 113.

The report as to Inventive Step was positive (YES) with respect to claims 5, 8, 9, 12, 35-37, 50-52, 57-60, 62-68, 83-85, 88-92, 94, 97-100, 103-106, 111, 114, 115.

The report as to Inventive Step was negative (NO) with respect to claims 1-4, 6, 7, 10, 11, 13-34, 76-78, 82, 95, 96, 101, 102, 107-110, 112, 113.

The report as to Industrial Applicability was positive (YES) with respect to claims 1-37, 50-52, 57-60, 62-68, 75-78, 82-85, 88-92, 94-15.

The report as to Industrial Applicability was negative (NO) with respect to claims NONE.

PA 1367636

## PATENT COOPERATION TREATY

REC'D 02 NOV 2000

WIPO

PCT

**PCT**

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 5063.01	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/US98/03178	International filing date (day/month/year) 19 FEBRUARY 1998	Priority date (day/month/year) 19 FEBRUARY 1997
International Patent Classification (IPC) or national classification and IPC IPC(7): A61M 25/00; and US Cl.: 604/280		
Applicant CONANCO MEDICAL DEVICES CORPORATION P		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 4 sheets.

This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority. (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 4 sheets.

3. This report contains indications relating to the following items:

- I  Basis of the report
- II  Priority
- III  Non-establishment of report with regard to novelty, inventive step or industrial applicability
- IV  Lack of unity of invention
- V  Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI  Certain documents cited
- VII  Certain defects in the international application
- VIII  Certain observations on the international application

RECEIVED  
JAN 16 2001  
TC 3700 MAIL ROOM

**CORRECTED  
VERSION**

Date of submission of the demand 18 SEPTEMBER 1998	Date of completion of this report 04 JUNE 1999
Name and mailing address of the IPEA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231	Authorized officer <i>R. Lee Palmer</i> SHARON KENNEDY
Facsimile No. (703) 305-3230	Telephone No. (703) 305-0154

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US98/03178

**I. Basis of the report**

## 1. With regard to the elements of the international application:\*

 the international application as originally filed the description:

pages \_\_\_\_\_ (See Attached) \_\_\_\_\_, as originally filed

pages \_\_\_\_\_, filed with the demand

pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_

 the claims:

pages \_\_\_\_\_ (See Attached) \_\_\_\_\_, as originally filed

pages \_\_\_\_\_, as amended (together with any statement) under Article 19

pages \_\_\_\_\_, filed with the demand

pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_

 the drawings:

pages \_\_\_\_\_ (See Attached) \_\_\_\_\_, as originally filed

pages \_\_\_\_\_, filed with the demand

pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_

 the sequence listing part of the description:

pages \_\_\_\_\_ (See Attached) \_\_\_\_\_, as originally filed

pages \_\_\_\_\_, filed with the demand

pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_

## 2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language \_\_\_\_\_ which is:

 the language of a translation furnished for the purposes of international search (under Rule 23.1(b)). the language of publication of the international application (under Rule 48.3(b)). the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

## 3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

 contained in the international application in printed form. filed together with the international application in computer readable form. furnished subsequently to this Authority in written form. furnished subsequently to this Authority in computer readable form. The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished. The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.4.  The amendments have resulted in the cancellation of: the description, pages \_\_\_\_\_ NONE the claims, Nos. \_\_\_\_\_ NONE the drawings, sheets/fig. \_\_\_\_\_ NONE5.  This report has been drawn as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).\*\*

\* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

\*\*Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US98/03178

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement****1. statement**

Novelty (N)	Claims <u>(Please See supplemental sheet)</u>	YES
	Claims <u>(Please See supplemental sheet)</u>	NO
Inventive Step (IS)	Claims <u>(Please See supplemental sheet)</u>	YES
	Claims <u>(Please See supplemental sheet)</u>	NO
Industrial Applicability (IA)	Claims <u>(Please See supplemental sheet)</u>	YES
	Claims <u>(Please See supplemental sheet)</u>	NO

**2. citations and explanations (Rule 70.7)**

Claims 1-3, 6, 7, 10, 11, 13-34, 42, 43, 45-47, 49 and 76-78 lack novelty under PCT Article 33(2) as being anticipated by Weinberger. Weinberger discloses a catheter (5) with a conduit (6), and a bulk (5a).

Claims 1-4 lack novelty under PCT Article 33(2) as being anticipated by Calderon. Calderon discloses a catheter with a conduit, and a plurality of bulks (56)(22).

Claims 95, 96, 98, 101, 102, 107-110, 112 113 and 116-118 lack novelty under PCT Article 33(2) as being anticipated by Liprie. Liprie discloses a drive cable (110) with a radioactive portion (10).

Claims 5, 8, 9, 12, 35-41, 44, 48, 50-75, 79-94, 97-100, 103-106, 111, 114, 115 and 119 meet the criteria set out in PCT Article 33(2)(4) because the prior art does not teach or fairly suggest the donut radioactive parts, or the balloon which bends the catheter.

**----- NEW CITATIONS -----**

NONE

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US98/03178

**Supplemental Box**

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: Boxes I - VIII

Sheet 10

**I. BASIS OF REPORT:**

This report has been drawn on the basis of the description,  
page(s) 1-78, as originally filed.

page(s) NONE, filed with the demand.

and additional amendments:

NONE

This report has been drawn on the basis of the claims,

page(s) NONE, as originally filed.

page(s) NONE, as amended under Article 19.

page(s) NONE, filed with the demand.

and additional amendments:

Claims 1-119, filed with the letter of 05 March 1999.

This report has been drawn on the basis of the drawings,

page(s) 1-60, as originally filed.

page(s) NONE, filed with the demand.

and additional amendments:

NONE

This report has been drawn on the basis of the sequence listing part of the description:

page(s) NONE, as originally filed.

pages(s) NONE, filed with the demand.

and additional amendments:

NONE

**5. (Some) amendments are considered to go beyond the disclosure as filed:**

NONE

**V. 1. REASONED STATEMENTS:**

The report as to Novelty was positive (YES) with respect to claims 5, 8, 9, 12, 25-41, 44, 48, 50-75, 79-94, 97-100, 102, 106, 111, 114, 115, 119.

The report as to Novelty was negative (NO) with respect to claims 1-4, 6, 7, 10, 11, 13-34, 42, 43, 45-47, 49, 76-78, 96, 96, 101, 102, 107-110, 112, 113, 116-118.

The report as to Inventive Step was positive (YES) with respect to claims 5, 8, 9, 12, 35-41, 44, 48, 50-75, 79-94, 97-100 102-106, 111, 113, 115, 119.

The report as to Inventive Step was negative (NO) with respect to claims 1-4, 6, 7, 10, 11, 13-34, 42, 43, 45-47, 49 76-78, 95, 96, 101, 102, 107-110, 112, 113 116-118.

The report as to Industrial Applicability was positive (YES) with respect to claims 1-119.

The report as to Industrial Applicability was negative (NO) with respect to claims NONE.

1

CLAIMS

What is claimed is:

1. A catheter assembly, comprising:

(a) a flexible tubular catheter body having an inner lumen;

and

6 (b) at least one fluid communication structure integrally formed on the catheter body, the at least one fluid communication structure adapted to permit fluid flow along the catheter body and through a biological path.

2. The catheter of claim 1, wherein each fluid communication

11 structure comprises:

(a) at least one bulk formed on the catheter body; and

(b) at least one conduit formed on the bulk, wherein the at least one conduit is adapted to permit fluid flow through a biological path.

16 3. The catheter of claim 2, wherein a radiating source is disposed within the inner lumen.

4. The catheter of claim 2, wherein the catheter has a plurality of bulks on the catheter body.

5. The catheter of claim 4, wherein each bulk has a length, the 21 length of each bulk being approximately three to seven millimeters.

6. The catheter of claim 1, further comprising at least one marker attached to the catheter body, wherein the marker enables a user to position a radiating source within a biological path.

26 7. The catheter of claim 2, further comprising at least one balloon attached to a distal end of the outer surface of the catheter body.

8. The catheter of claim 7, wherein the at least one balloon extends over the at least one bulk.

- 1        9.     The catheter of claim 8, wherein the at least one balloon extends over each conduit on a bulk such that the path for the fluid is formed by the conduit and the balloon.
10.     The catheter of claim 8, wherein a balloon control communicates with the balloon through the inner lumen or micro conduits.
- 6        11.    A catheter assembly, comprising:
  - (a) a flexible tubular catheter body having an inner lumen and a guidewire channel;
  - (b) a guidewire disposed within the guidewire channel for selectively positioning the catheter body;
  - (c) a first balloon structure attached to a distal end of the catheter body, wherein the balloon is in communication with a balloon control through micro conduits;
  - (d) a guidewire exit port in communication with the guidewire channel; and
  - 16        (e) at least one perfusion hole at a proximal side of the first balloon structure and at least one perfusion hole at a distal side of the first balloon structure to permit fluid flow through a biological path.
- 11        12.    The catheter of claim 11, further comprising a second balloon enveloping the first balloon structure.
- 16        13.    A catheter for use in biological paths to provide fluids and/or gases perfusion along the length of the catheter when inserted in a biological path, wherein the catheter comprises two or more integral concentric or non concentric conduits; a more interior conduit used for placing devices used in catheter operations; a more exterior conduit for providing a track for fluids and/or gases without substantially obstructing fluid flow through the biological paths, wherein the catheter provides a continuous wall for the more exterior conduit.
- 26

TPEAUS 05 MAR 1999

- 1        14. A catheter for use in biological paths to provide fluids and/or gases perfusion along the length of the catheter when inserted in a biological path, wherein the catheter comprises two or more integral concentric or non concentric conduits and one or more balloons attached to a more exterior conduit; a more interior conduit used for placing devices used in catheter operations; the more exterior conduit for providing a track for fluids and/or gases without substantially obstructing fluid flow through the biological paths when the one or more balloons are inflated, wherein the one or more balloons, when inflated, provide a wall for the more exterior conduit.
- 6        15. A catheter according to claim 13 or 14, where the exterior conduit permits positioning a radiation and/or radioactive source at a desirable distance from the biological paths.
- 11      16. A catheter according to claim 13 or 14, where the exterior conduit supports the walls of the biological paths.
- 16      17. A catheter according to claim 13 or 14, where the exterior conduit is of flexible material.
- 21      18. A catheter according to claim 13 or 14, where the exterior conduit prolongate along the entire length of the interior conduit.
19.      19. A catheter according to claim 13 or 14, where the exterior conduit are segments of conduits located along the entire length and/or at specific locations of the interior channel.
20.      20. A catheter according to claim 13 or 14, where the exterior conduit have perpendicular to its cross section micro-conduits and/or pores.
- 26      21. A catheter according to claim 20, where the cross section of the micro-conduits and/or pores are parallelepipeds of regular or irregular shape.

TPEAUS - 05 MAR 1999

- 1        22. A catheter according to claim 21, where the cross section of the micro-conduits and/or pores are circles, ellipses and/or rectangles.
23. A catheter according to claim 20, where the micro-conduits and/or pores are arranged in an ordered manner and/or non-ordered manner.
- 6        24. A catheter according to claim 13 or 14, where the interior conduits are used for introducing devices used in catheter operations.
25. A catheter according to claim 24, where the devices used in catheter operations are radiation and/or radioactive sources.
- 11      26. A catheter according to claim 24, where the devices used in catheter operations are guidewires.
27. A catheter according to claim 13 or 14, where the exterior conduit can have around the whole or partial periphery open channels.
28. A catheter according to claim 27, where the walls of the open channels have regular or irregular shape.
- 16      29. A catheter according to claim 27, where the open channels are arranged in an ordered manner and/or non-ordered manner.
30. A catheter according to claim 14, where the balloon constitutes a concentric or non concentric most external conduit with respect to the interior and exterior conduits.
- 21      31. A catheter according to claim 14, where around the whole or partial periphery and at specific location of the exterior conduit are attached one or more balloons.
32. A catheter according to claim 14, where the balloon prolongate along the entire length of the exterior conduit.
- 26      33. A catheter according to claim 32, where the ends of the balloons are attached to distal locations of the edges of the external conduit.
34. A catheter according to claim 14, where the balloons are located at specific locations along the entire length of the exterior conduit.

- 1        35. A catheter according to claim 13 or 14, where said external conduits having on its outer surface pores which extend from said outer surface to the above mentioned micro-conduits, being said pores oriented at whatever desired angle with respect to the micro-conduits.
- 6        36. The catheter of claim 19, wherein the segments and the space between the segments are covered by a membrane.
37. The catheter of claim 27, wherein the open channels are covered by a membrane.
38. The catheter of any one of claims 1 to 14 wherein the catheter includes a valve.
- 11      39. The catheter of claim 38 wherein the valve is a U-shaped metallic valve built into a lumen or channel of the catheter.
40. The catheter of claim 38 wherein the catheter has multiple valves.
41. The catheter of any one of claims 1 to 14 wherein the catheter further comprises a pressure monitor or a blood pressure monitor.
- 16      42. The catheter of any one of claims 1 to 14 wherein the catheter further comprises a marker.
43. The catheter of claim 42 wherein the marker is for visually marking the catheter with visual monitoring equipment.
- 21      44. The catheter of any one of claims 1 to 14 further comprising a stent or membrane for maintaining a cell wall.
45. The catheter of any one of claims 1 to 14 further comprising a guidewire.
- 26      46. The catheter of claim 45 further comprising a second guidewire, wherein at least one of the guidewires is made of nickel alloy.
47. The catheter of any one of claims 1 to 14 further comprising an over-the-wire guidewire.

TPEAU 05 MAR 1999

- 1        48. The catheter of any one of claims 1 to 14 wherein an automatic radiating source placement machine is used with the catheter and wherein the radiating source is made of iridium or strontium.
- 6        49. The catheter of any one of claims 1 to 14 wherein a guidewire may be removed from the catheter and another wire placed into the catheter.
- 11      50. A method for using a medical procedure comprising the following steps:  
                a guidewire is placed into a biological path and beyond a place where treatment is to occur;
- 16      a catheter is placed into the biological path using a rail system attached to the distal end of a closed channel;  
                when a fluid communication structure is placed in the place where treatment is to occur a balloon is inflated; and  
                the guidewire is then removed and an irradiation source is placed in the closed channel or an inner lumen.
- 21      51. The method of claim 50 wherein  
                a second guidewire is placed in the closed channel formed in the inner lumen to assist the introduction of the catheter in the biological path.
- 26      52. The method of claim 50, 51 wherein an over-the-wire, monorail, or multiple wire, techniques is used for insertion of the catheter.
53. The method of claim 50 or 51, wherein an irradiation source is placed in the inner lumen and a guidewire may be used to move the irradiation source to the distal end or near the distal end of the closed channel of the inner lumen using an automatic machine to move the irradiation source to the distal end of the channel.
54. The method of claim 50 or 51, wherein once the catheter body is in place at the biological path, the perfusion holes and allow fluids

- 1 or gases to flow through the catheter body, thereby preventing an occlusion at the biological path where treatment is occurring.
55. The method of claim 50 or 51, wherein depending on whether the irradiation source needs to be centered a catheter having an appropriate fluid communication structure may be chosen.
- 6 56. The method of claim 50 or 51, wherein further comprising the step of:
  - removing the guidewire.
57. A catheter for infusing drugs to a localized area of the wall of a biological path comprising:
  - means for generating a trap against the wall; and
  - means for infusing a drug into the trap.
- 11 58. The catheter of claim 57 wherein the means for generating a trap comprises a balloon.
59. The catheter of claim 57 or 58 wherein the means for generating a trap comprises a transverse wavy balloon.
- 16 60. The catheter of claim 57 or 58 wherein the means for generating a trap comprises a two ring shaped balloons.
61. The catheter of claim 57 or 58, wherein means for infusing drugs comprises an infusion port.
- 21 62. A method for infusing drugs using a catheter comprising the steps of:
  - creating a trap against a wall of a biological path; and
  - providing the drug to the created trap.
63. The method of claim 62 wherein the step of creating the trap comprises:
  - inflating a balloon.
- 26

TPEAUS 05 MAR 1999

- 1        64. The method of claim 62 or 63 wherein the step of providing the drug comprises dispensing the drug under pressure through an infusion port.
65. A method for centering a lumen in a two lumen catheter comprising:
- 6                inflating balloons positioned to center one lumen and displace the second lumen wherein the second lumen is not centered.
66. A system for medical procedures to be used in biological pathway comprising:
- 11                an inflator tube for inflating other tubes; at least one inflatable tube operably connected to the inflator tube which can be inflated by the inflator tube while in a biological pathway;
- 16                a form, connected to the inflator tube and at least one inflatable tube, wherein the form maintains or assists in maintaining the relative position of the inflator tube to at least one inflatable tube.
67. The system of claim 66, wherein the system is attached to a catheter.
- 21                68. The system of claim 66 or 67, wherein the system further comprises two ends an entry end and a distal end; and wherein the system slides onto a catheter, wherein the catheter may pass from the entry end through the system to the distal end.
- 26                69. The system of claim 66 or 67 wherein the system further comprises a catheter, whereby the catheter may be slid through the other components of the system while the system is deployed in a biological pathway.
70. The system of 66 or 67 wherein the catheter is inside one tube, either the inflator tube or one of the inflatable tubes.

IPEA/US 05 MAR 1999

- 1        71.     The system of 66 or 67 wherein the form comprises a body and a series arms; and  
              wherein each arm fits into or slides into a tube, and wherein the body fits into either the inflator tube, the entry end, or the distal end of the system.
- 6        72.     The system of 66 or 67 wherein the system has two, three, four, five six, or seven inflatable tubes, and wherein each inflatable tube has two ends and each end is directly or indirectly connected to the inflator tube.
- 11      73.     The system of 66 or 67 wherein the inflator tube comprises one or more microforms wherein the microforms are used to inflate one or more inflatable tubes, whereby one or more microforms are used to inflate each inflatable tube.
- 16      74.     The system of 66 or 67 wherein the inflator tube comprises openings or passageways in which the form is positioned or passes through the opening or passageway.
- 21      75.     The system of 66 or 67 used in a biological pathway with walls, wherein the inflator tube comprises an entry end and a distal end, and whereby the inflator tubes and the inflatable tubes are generally parallel to each other and to the walls of the biological pathway.
- 21      76.     A method for guiding a catheter to a coronary artery and around curves or bends in the artery comprising:  
              guiding a guiding catheter to the vicinity of a coronary artery;  
              inserting a preformed coronary wire into the catheter;  
              guiding the guiding catheter around or past the curve or bend in the coronary artery.
- 26      77.     The method of claim 76 wherein the step of guiding the guiding catheter to the artery is performed with a guidewire.
- 26      78.     The method of claim 76 or 77, further comprising the step of:

IPEA/US 05 MAR 1999

- 1 removing the guidewire from the guiding catheter.
79. The method of claim 76 or 77 further comprising the step of: replacing the guidewire from the catheter with the preformed coronary wire.
80. The method of 76 or 77, wherein the coronary artery is the left coronary artery and the curve or bend is the aorta arch of the left coronary artery and the preformed coronary wire is a preformed left coronary wire.
- 6 81. The method of any one of claims 76 or 77, wherein the coronary artery is the right coronary artery and the curve or bend is the entrance of the right coronary artery and the preformed coronary wire is a preformed right coronary wire.
- 11 82. A balloon for changing the flexion of a catheter comprising: an inflatable balloon attached to a catheter near its distal end, wherein the balloon is longer in the longitudinal direction and is attached to the catheter in a longitudinal direction and whereby inflating or deflating the balloon bends the catheter primarily in its longitudinal direction so that inflating and deflating of the balloon assists in guiding the catheter through a curvature in a passageway.
- 16 83. A system for changing the flexion of a catheter having a length comprising:
  - a membrane, connected at two different longitudinal positions along the length of the catheter;
  - an inflatable balloon, situated between the membrane and the catheter and in between the two longitudinal positions; whereby if the balloon is inflated the catheter flexion is changed.
- 21 84. The system of claim 83 wherein the length of the membrane between the two longitudinal positions is equal to or longer than the

- 1 distance between the two longitudinal positions, whereby inflating the balloon causes the membrane to pull the two longitudinal positions closer together causing the catheter to flex.
85. The system of claims 83 or 84 wherein the balloon is attached either to the membrane or to the catheter, wherein the balloon is positioned between the outer wall of the catheter and the inner wall of the membrane.
- 6 86. The system of 83 or 84 wherein the membrane has a resting state, and wherein the inflated balloon engages the membrane and distorts or changes the shape of the membrane from its resting state prior to engagement.
- 11 87. The system of 83 or 84 wherein the two longitudinal positions are radially in the same radial location or measurement on the catheter so that the catheter does not twist when the balloon is inflated.
88. A system for changing the flex of a catheter during use of the catheter in a biological pathway comprising:
  - 16 an object, connected to a catheter with two active locations, wherein placing pressure on the object by engaging or pulling the object causes the catheter to flex in the vicinity of the two active locations.
- 21 89. The system of claim 88 wherein the object is engaged or pulled and the distance between the two active locations is shortened or lessened.
90. The system of 88 or 89 wherein the object is a membrane, the membrane is attached at the two active locations to the catheter, and the membrane is engaged.
- 26 91. The system of 88 or 89 wherein the object is a cord, the cord runs most of the length of the catheter and whereby, when the cord is

PEAUS - 05 MAR 1999

1 engaged or pulled, the cord applies a tension between the two active locations.

92. The system of claim 91 wherein the cord runs most of the length of the catheter inside a conduit, lumen or rail of the catheter.

6 93. The system of claim 89 wherein there are more than two active locations on the catheter.

94. A method for flexing a catheter during the process of guiding a catheter in a biological pathway, comprising:

placing the catheter in the biological pathway;

guiding the catheter to a curved area of the biological pathway;

11 engaging or pulling an object which is connected or makes contact with the catheter in at least two locations;

16 whereby the engaging or pulling of the object causes the catheter to flex in the general area of the at least two locations and assists in guiding the catheter through or passed the curve in the biological pathway.

95. A radioactive wire for use in medical procedures comprising:

a drive cable which is non-radioactive;

a radioactive portion wherein the drive cable has a greater length than the radioactive portion; and

21 a lockable connection between the drive cable and the radioactive portion.

96. The radioactive wire of claim 95 wherein the radioactive portion comprises radioactive parts comprising:

26 one or more of the following: cylinders, donuts, washers, stoppers.

97. The radioactive wire of claim 95 wherein the radioactive portion comprises a coil which is connected to the drive cable.

- 1      98.    The radioactive wire of claim 95, 96 or 97 wherein the lockable connection comprises a push-in connection.
99.    The radioactive wire of claim 98 wherein the lockable connection comprises a slot and the radioactive portion comprises a stopper.
- 6      100.   The radioactive wire of claim 95, 96, or 97 wherein the drive cable comprises a stud and the radioactive portion fits around the stud.
101.   A wire for use in medical treatments using radiation comprising:
  - a drive cable having a length greater than diameter;
  - a stud connected to the drive cable; and
  - one or more radioactive parts wherein the radioactive parts fit over the stud on the drive cable.
102.   The wire of claim 101 wherein the radioactive parts are locked into place on the stud.
- 16     103.   The wire of claim 101, or 102 wherein one of the radioactive parts is a stopper.
104.   The wire of claim 101, or 102 wherein the radioactive parts are one or more of the following: cylinder, washer, coil, stopper.
105.   The wire of claim 101 or 102, wherein the stud is connected to the drive cable by a weld.
- 21     106.   The wire of claim 101 or 102 wherein the drive cable is formed from metal and wherein the stud is formed from same metal cable as the drive cable.
107.   A radioactive wire for use in a medical procedure comprising:
  - a first portion which is substantially or completely non-radioactive;
  - a second portion which is radioactive; and

IPEA/US 05 MAR 1999

1           a connection between the first portion and the second portion, wherein the second portion is configurally connected to the first portion via the connection.

108. The radioactive wire of claim 107 wherein the second portion is configurally connected to the first portion by a push-in connection.

6           109. The radioactive wire of claim 108 wherein the push-in connection is permanent connection.

110. The radioactive wire of claim 107, or 108 wherein the connection is a slot connection.

11          111. The radioactive wire of claim 107 wherein the second portion is made of interchangeable radioactive parts.

112. The radioactive wire of claim 111 wherein the interchangeable radioactive parts are made up of one or more of the following: cylinder, donut, washer, coil, lockable stopper.

16          113. The radioactive wire of claim 107, 111, or 112 wherein the first portion comprises a stud.

114. The radioactive wire of claim 107 wherein the second portion is made of one or more radioactive donuts which are placed on the stud.

115. The radioactive wire of claim 114 wherein the radioactive donuts are locked in place on the stud.

21          116. The radioactive wire of claim 107, 108, 109, 111, 112, 114, or 115 wherein the radioactive wire is placed in a catheter.

117. The radioactive wire of claim 107, 108, 109, 111, 112, 114, or 115 wherein the radioactive portion has a length of between 3mm and 30mm.

26          118. The radioactive wire of claim 107, 108, 109, 111, 112, 114, or 115 wherein the radioactive portion has a diameter of between .33mm and 1mm.

119. The radioactive wire of claim 107, 108, 109, 111, 112, 114, or 115 wherein the radioactive portion has a lockable stopper.

## PATENT COOPERATION TREATY

## PCT

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 5063.01	<b>FOR FURTHER ACTION</b> See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/US98/03178	International filing date (day/month/year) 19 FEBRUARY 1998	Priority date (day/month/year) 19 FEBRUARY 1997
International Patent Classification (IPC) or national classification and IPC IPC(6): A61M 25/00; and US Cl.: 604/280		
Applicant CONDADO MEDICAL DEVICES CORPORATION		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

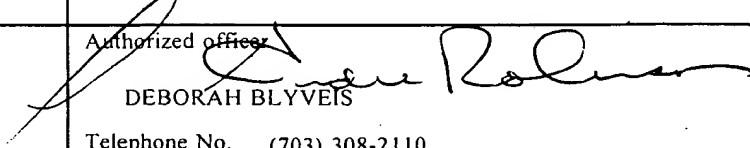
2. This REPORT consists of a total of 5 sheets.

This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority. (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 0 sheets.

3. This report contains indications relating to the following items:

- I  Basis of the report
- II  Priority
- III  Non-establishment of report with regard to novelty, inventive step or industrial applicability
- IV  Lack of unity of invention
- V  Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI  Certain documents cited
- VII  Certain defects in the international application
- VIII  Certain observations on the international application

Date of submission of the demand 18 SEPTEMBER 1998	Date of completion of this report 04 JUNE 1999
Name and mailing address of the IPEA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231	Authorized officer  DEBORAH BLYVEIS
Facsimile No. (703) 305-3230	Telephone No. (703) 308-2110

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US98/03178

**I. Basis of the report**

1. This report has been drawn on the basis of (Substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain

 the international application as originally filed. the description, pages 1-78, as originally filed.pages NONE, filed with the demand.pages NONE, filed with the letter of \_\_\_\_\_.pages       , filed with the letter of \_\_\_\_\_. the claims, Nos. 1-119, as originally filed.Nos. NONE, as amended under Article 19.Nos. NONE, filed with the demand.Nos. NONE, filed with the letter of \_\_\_\_\_.Nos.       , filed with the letter of \_\_\_\_\_. the drawings, sheets/fig 1-60, as originally filed.sheets/fig NONE, filed with the demand.sheets/fig NONE, filed with the letter of \_\_\_\_\_.sheets/fig       , filed with the letter of \_\_\_\_\_.

2. The amendments have resulted in the cancellation of:

 the description, pages NONE. the claims, Nos. NONE. the drawings, sheets/fig NONE.

3.  This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the **Supplemental Box** Additional observations below (Rule 70.2(c)).

4. Additional observations, if necessary:

NONE

**III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

The question whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been and will not be examined in respect of:

- the entire international application.  
 claims Nos. 38-49, 53-56, 61, 79-81, 86, 87, 93, 116-119

because:

- the said international application, or the said claim Nos. relate to the following subject matter which does not require international preliminary examination (*specify*).

- the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*).

- the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

- no international search report has been established for said claims Nos. (See Attached).

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US98/03178

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement****1. STATEMENT**

Novelty (N)	Claims <u>(Please See supplemental sheet)</u>	YES
	Claims <u>(Please See supplemental sheet)</u>	NO
Inventive Step (IS)	Claims <u>(Please See supplemental sheet)</u>	YES
	Claims <u>(Please See supplemental sheet)</u>	NO
Industrial Applicability (IA)	Claims <u>(Please See supplemental sheet)</u>	YES
	Claims <u>(Please See supplemental sheet)</u>	NO

**2. CITATIONS AND EXPLANATIONS**

Claims 1-3, 6, 7, 10, 11, 13-34, 76-78 and 82 lack novelty under PCT Article 33(2) as being anticipated by Weinberger. Weinberger discloses a catheter (5) with a conduit (6), and a bulk (5a).

Claims 1-4 lack novelty under PCT Article 33(2) as being anticipated by Calderon. Calderon discloses a catheter with a conduit, and a plurality of bulks (56)(22).

Claims 95, 96, 101, 102, 107-110, 112 and 113 lack novelty under PCT Article 33(2) as being anticipated by Liprie. Liprie discloses a drive cable (110) with a radioactive portion (10).

Claims 5, 8, 9, 12, 35-37, 50-52, 57-60, 62-68, 83-85, 88-92, 94, 97-100, 103-106, 111, 114 and 115 meet the criteria set out in PCT Article 33(2)-(4) because the prior art does not teach or fairly suggest the donut radioactive parts.

----- NEW CITATIONS -----

NONE

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US98/03178

**Supplemental Box**

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: Boxes I - VIII

Sheet 10

**III. NON-ESTABLISHMENT OF REPORT:**

No international search report has been established for claim numbers 38-49, 53-56, 61, 69-75, 79-81, 86, 87, 93, 116-119.

**V. 1. REASONED STATEMENTS:**

The report as to Novelty was positive (YES) with respect to claims 5, 8, 9, 12, 35-37, 50-52, 57-60, 62-68, 83-85, 88-92, 94, 97-100, 103-106, 111, 114, 115.

The report as to Novelty was negative (NO) with respect to claims 1-4, 6, 7, 10, 11, 13-34, 76-78, 82, 95, 96, 101, 102, 107-110, 112, 113.

The report as to Inventive Step was positive (YES) with respect to claims 5, 8, 9, 12, 35-37, 50-52, 57-60, 62-68, 83-85, 88-92, 94, 97-100, 103-106, 111, 114, 115.

The report as to Inventive Step was negative (NO) with respect to claims 1-4, 6, 7, 10, 11, 13-34, 76-78, 82, 95, 96, 101, 102, 107-110, 112, 113.

The report as to Industrial Applicability was positive (YES) with respect to claims 1-37, 50-52, 57-60, 62-68, 75-78, 82-85, 88-92, 94-15.

The report as to Industrial Applicability was negative (NO) with respect to claims NONE.

# PATENT COOPERATION TREATY

From the  
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To: ALDO NOTO  
DORSEY & WHITNEY LLP  
1330 CONNECTICUT AVENUE, N. W., SUITE 200  
WASHINGTON, D.C. 20036

**PCT**

## NOTIFICATION OF TRANSMITTAL OF INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Rule 71.1)

Date of Mailing  
(day/month/year)

**16 JUN 1999**

Applicant's or agent's file reference  5063.01	<b>IMPORTANT NOTIFICATION</b>	
International application No.  PCT/US98/03178	International filing date (day/month/year)  19 FEBRUARY 1998	Priority Date (day/month/year)  19 FEBRUARY 1997
Applicant  CONDADO MEDICAL DEVICES CORPORATION		

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.
4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices)(Article 39(1))(see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

**ROUTINED**

*Jul 20-99*

Name and mailing address of the IPEA/US  
Commissioner of Patents and Trademarks  
Box PCT  
Washington, D.C. 20231  
Telephone No. (703) 308-2220

Authorized officer  
*Andrea Robinson*  
DEBORAH BLYVEIS

Telephone No. (703) 308-2110